June 11, 2003

Ann Tveit, Ph.D., DABT
ATOFINA Chemicals
2000 Market Street
Philadelphia, PA 19103

Dear Dr. Tveit:

The Office of Pollution Prevention and Toxics is transmitting EPA's comments on the robust summaries and test plan for Methanesulphonic acid posted on the ChemRTK HPV Challenge Program Web site on February 5, 2003. I commend ATOFINA Chemicals, Inc and Chevron Phillips Chemical Company LP for their commitment to the HPV Challenge Program.

EPA reviews test plans and robust summaries to determine whether the reported data and test plans will provide the data necessary to adequately characterize each SIDS endpoint. On its Challenge Web site, EPA has provided guidance for determining the adequacy of data and preparing test plans used to prioritize chemicals for further work.

EPA will post this letter and the enclosed comments on the HPV Challenge Web site within the next few days. As noted in the comments, we ask that ATOFINA Chemicals, Inc and Chevron Phillips Chemical Company LP advise the Agency, within 60 days of this posting on the Web site, of any modifications to its submission.

If you have any questions about this response, please contact Richard Hefter, Chief of the HPV Chemicals Branch, at 202-564-7649. Submit questions about the HPV Challenge Program through the "Contact Us" link on the HPV Challenge Program Web site pages or through the TSCA Assistance Information Service (TSCA Hotline) at (202) 554-1404. The TSCA Hotline can also be reached by e-mail at tsca-hotline@epa.gov.

I thank you for your submission and look forward to your continued participation in the HPV Challenge Program.

Sincerely,

-*S*-

Oscar Hernandez, Director
Risk Assessment Division

Enclosure

cc: W. Penberthy
M. E. Weber

EPA Comments on Chemical RTK HPV Challenge Submission:
Methanesulphonic Acid

Summary of EPA Comments

The sponsor, ATOFINA Chemicals, Inc., submitted a test plan and robust summaries to EPA for Methanesulphonic Acid (CAS No. 75-75-2) dated January 10, 2003. EPA posted the submission on the ChemRTK HPV Challenge Website on February 5, 2003.

EPA has reviewed this submission and has reached the following conclusions:

1. Physicochemical Properties and Environmental Fate. Adequate data are available for all endpoints. The submitter needs to include experimental details in the robust summary for vapor pressure.

2. Health Effects. Available data on acute, repeated-dose, and genetic toxicity are adequate for the purposes of the HPV Challenge Program. EPA reserves judgement on the adequacy of the developmental toxicity data pending submission of additional information. EPA recommends that the submitter conduct a combined reproduction/developmental toxicity screening test to adequately address these endpoints instead of the proposed 90-day repeated-dose toxicity test.

3. Ecological Effects. The acute toxicity data for fish, invertebrates, and algae are adequate for the purposes of the HPV Challenge Program.

EPA requests that the submitter advise the Agency within 60 days of any modifications to its submission.

EPA Comments on the Methanesulphonic Acid Challenge Submission

Test Plan

General Comments.

The submitted test plan lacks a rationale for the test protocol proposed (OECD TG 408) to meet the reproductive toxicity endpoint.

Physicochemical Properties (melting point, boiling point, vapor pressure, partition coefficient and water solubility).

Adequate data are available for all endpoints for the purposes of the HPV Challenge Program. The submitter needs to include experimental details in the robust summary for vapor pressure.

Water Solubility. The submitter needs to address the discrepancy between the value reported in the test plan (1000 g/mL) and the one reported in the robust summary (100 vol% which corresponds to 1000g/L) .

Environmental Fate (photodegradation, stability in water, biodegradation, fugacity).

Adequate data are available for all endpoints for the purposes of the HPV Challenge Program. EPA agrees with the submitter's approach for stability in water.

Health Effects (acute toxicity, repeated-dose toxicity, genetic toxicity, and reproductive/developmental toxicity).

Adequate data are available to address acute, repeated-dose, and genetic toxicity endpoints for the purposes of the HPV Challenge Program. EPA reserves judgement on the adequacy of the developmental toxicity data pending submission of additional information. EPA recommends that the submitter conduct a combined reproduction/developmental toxicity screening test (OECD TG 421) to adequately address the reproduction toxicity endpoint instead of the proposed 90-day repeated-dose toxicity test (OECD TG 408).

Reproduction Toxicity. The submitter did not provide data on the reproduction toxicity endpoint and has indicated in the data matrix, Table 1, "Testing Proposed (OECD 408)" to address this endpoint. OECD TG 408 is a guideline for evaluating 90-day repeated-dose toxicity. The submitter did not explain the intention for this proposed test since the repeated-dose toxicity endpoint has been addressed by a 4-week inhalation toxicity study. EPA's guidance states that evaluation of reproductive organs in an **existing 90-day repeated-dose toxicity study** and the availability of an adequate developmental toxicity study will be sufficient to address these endpoints. Therefore, EPA recommends that the submitter conduct a Combined Reproduction/Toxicity Screening Test according to OECD TG 421 (via gavage) instead of the proposed OECD TG 408 to adequately address this endpoint.

Developmental Toxicity. The developmental toxicity study does not appear to have been conducted at the maximum tolerated dose (MTD) (the maternal and developmental toxicity NOAELs were the highest dose tested). Therefore, EPA recommends that the submitter either provide the range-finding data for this study to confirm the MTD or conduct a Reproduction/Developmental Toxicity Screening Test according to OECD TG 421 (via gavage).

Ecological Effects (fish, invertebrates, and algae).

Adequate data are available for all endpoints for the purposes of the HPV Challenge Program.

Specific Comments on the Robust Summaries

Physicochemical Properties

The submitter needs to include experimental details in the robust summary for vapor pressure.

Followup Activity

EPA requests that the submitter advise the Agency within 60 days of any modifications to its submission.